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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,008	12/20/2000	Marina Chuenkova	1322.1028-001	7228
21005	7590	10/21/2003	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.			TURNER, SHARON L	
530 VIRGINIA ROAD			ART UNIT	
P.O. BOX 9133			PAPER NUMBER	
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DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/745,008

**Applicant(s)**

CHUENKOVA ET AL.

**Examiner**

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-33 and 42-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-33 and 42-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 25-33 and 42-58 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### Response to Amendment

1. The amendment filed 8-01-03 has been entered into the record and has been fully considered.
2. Claims 34-39 are canceled. Claims 25-33 and 42-58 are pending.
3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

### Rejections Necessitated by Amendment

#### Election/Restriction

5. Applicant's arguments with respect to claims 51-58 in the response of 8-1-03 are deemed persuasive and the claims have been rejoined.

#### ***Claim Rejections - 35 USC § 112***

6. Claims 25-33, 42-50 and 51-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Applicants point to support for the new claim recitations within Figure 26C, the sequence listing, at p. 8, 19, 21, 23-24, 29, 31, p. 41 and Table I. However, the Examiner fails to find support for the combination of elements that now define the claims. The recitations constitute new matter absent evidentiary support for the

YOU SHOULD SPECIFY NEW MATTER

combination of recitations now recited which serve to delineate a new genus not apparently contemplated at the time of filing. To obtain the benefit of the priority document applicant's should additionally note where such support may be found within the provisional application as the Examiner has been unable to find support for the combination of elements that now define the invention.

**Claim Rejections - 35 USC § 102 and 103**

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 25-27, 42-44 and 51-56 are rejected under 35 U.S.C. 102(b) as being anticipated by IDS reference AX, Pereira et al., J. Exp. Med., 174:179-91, 1991 or in the alternative under 35 USC 103(a) as obvious over IDS reference AX, Pereira et al., J. Exp. Med., 174:179-91, 1991.

Pereira et al., teaches trypanosoma cruzi Neuraminidase sequence corresponding with 100% identity to a peptide comprising SEQ ID NO:14. As the peptides apparently share the requisite structure they are the same and inherently provide for neurotrophic activity absent factual evidence to the contrary. Pereira teaches bacterial lysates in PBS comprising neuraminidase and exhibiting neuraminidase activity and thus the reference teaches compositions comprising the peptides with physiologically acceptable carriers. The N and C terminal amino acids represent adequate protecting groups. Applicant's point out the negative limitation that the peptide is not SEQ ID NO:34. However, Pereira is not limited to the peptide of SEQ ID NO:34 which is the sequence disclosed as the composite of TCNA and of clone 7F. The reference further teaches analysis of multiple clones via sequencing and immunoblot analysis from a  $\lambda$ ZAP protein expression library. As disclosed at p. 182, Clones 7F, 10C and 20G produced peptides with 180-170kD weight and that react with the TCN-2 antibody. It is further disclosed that these clones contain full-length copies of the TCNA gene. However, the sequences of these alternative full-length clones is not disclosed. While it is expected that the clones are either identical or largely similar, the Examiner cannot determine

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how the actual sequences differ in amino acid structure within the full length and thus cannot definitively establish that the sequences are in fact the same as SEQ ID NO:34 or are different in one or more residues. Based upon applicant's exclusion of SEQ ID NO:34 from the claim, the artisan cannot discern whether or not the alternative clones are within the metes and bounds of the claim. Moreover, Periera et al., also teach clone 16C that contains only part of the TCNA gene and displays a band of 60kD recognized by the TCNA antibody. The map indicates the general region as denoted by restriction fragments that correlate to the TCNA reading frame, but the Periera reference is silent as to the amino acids comprised within the partial clone. Thus, the Examiner cannot discern whether the 16C partial clone comprises SEQ ID NO:14.

The USPTO has insufficient resources to determine whether or not the proteins comprised within the 10C, 20G and 16C clones meet the claim limitations of 90% identity to SEQ ID NO:14, that is not SEQ ID NO:34. Thus, the Examiner has insufficient facts to determine whether the Periera et al., proteins are "inherently the same" or obvious variants since the examiner cannot determine how the cloned proteins differ. Since the record does not allow the determination of if and how the claimed products differ, the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Specifically, that the Periera proteins neither comprise 90% variants of SEQ ID NO:14 nor the sequence of SEQ ID NO:34. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977). The burden shifts to applicant's to show unobvious difference.

It is noted for the record that the alignment provided by Applicant's in traversal of

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the Chuenkova et al., reference apparently evidences that clone 19Y of Periera et al., is not within applicant's claims as the clone fails to bear 90% identity to SEQ ID NO:14 as evidenced by the alignment.

10. Claims 25-27, 42-44 and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over IDS reference AX, Pereira et al., J. Exp. Med., 174:179-91, 1991 in view of IDS reference Chuenkova et al., Biochem. & Biophys. Res. Comm., 262:549-556, 1999.

Pेरiera et al., teach as set forth above.

Pेरiera et al., is as set forth above and is relied on to the extent of the 102/103 rejection set forth therein. However, in addition Pेरiera et al., is relied on to the extent that it teaches a sequence comprising SEQ ID NO:14 and SEQ ID NO:34. Further Pेरiera et al., is further relied on <sup>WITH REGARD TO</sup> its teachings of the structure of the transsialidase protein, the enzyme activity and to the different portions of the molecule as identified for example in Figure 5, including with cysteine rich regions, Type III module, long terminal repeat and GPI-anchor. Pेरiera evidences that the N-terminal cysteine rich region is believed to possess the enzymatic activity, see in particular pp. 187 columns I-II, Cysteine rich domain. ✓

Chuenkova similarly teach a transsialidase peptide and regions corresponding to the Pेरiera et al., enzyme. Chuenkova further teaches the use of truncated or modified constructs of the transialidase to confirm the enzymatic region of the molecule as disclosed for example in Figure 2. Thus, one of skill in the art given the teachings of Chuenkova would be motivated to use deletion constructs of the Pेरiera et al. peptide in

order to confirm Periera's hypothesis that the N-terminal cysteine rich region is responsible for the enzymatic activity of the molecule. One of skill in the art would have expected positive results using the Chuenkova modifications based upon the cumulative reference teachings as to positive results with such constructs and the high skill in the art of recombinant DNA technology. Such modifications would result in molecules possessing the SEQ IDNO:14 motif but which were not full length SEQ ID NO:34. Thus, the cumulative reference teachings render obvious the claimed invention.

### **Status of Claims**

11. No claims are allowed.

### **Conclusion**

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.



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13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
October 15, 2003

*Gary L. Kunz*  
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